Congress of the United States
House of Representatives
Washington, DC 20515

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May 1, 1998

Michael A. Friedman, M.D.
Lead Deputy Commissioner
United States Food and Drug Administration
Mail Code HF-28
Room 14-71
Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Friedman:

As the Agency proceeds with the implementation of the Food and Drug Administration Modernization Act of 1997 (FDAMA), we thought it was important to clarify our intent in enacting Section 112, the fast track section. This is not a codification of the Agency's existing regulations, such as those covering accelerated approval; it also represents important new authority for the Agency,

In the past, FDA has demonstrated great flexibility in approving drugs to treat certain serious or life-threatening diseases such as AIDS and cancer. Section 112 was intentionally drafted to enable the Agency to use the same level of flexibility in all cases of serious or life. threatening conditions and whine there is the potential to address an unmet medical need.

It creates a new mechanism that can be used by the FDA to address those products that to dare have not been eligible for accelerated approval under Subpart E or Subpart H of your regulations. We intentionally included the reference to evidence from *clinical* endpoints to make clear that drugs are eligible for the fast track approach even if they were not evaluated on the basis of surrogate endpoints or measurements of mortality, and specifically if FDA might not view them as eligible under Subpart E or H.

In addition, we reminded the Agency that the evidence of efficacy for fast track drugs need not meet the Agency's "ordinary" standards for approval. Instead, as our report language makes clear, where 'the evidence of a drug's effect on a clinical endpoint strongly suggest effectiveness, but is not sufficiently conclusive to warrant ordinary approval,>' the Agency is authorized co approve a drug as a fast track product. If FDA believes further confirmation of efficacy is needed, it may require post-approval studies so that ultimate clinical benefit can be verified on the same post-approval basis as for accelerated approval products. This provision also

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authorizes FDA to remove the product from the market through an accelerated withdrawal procedure if clinical effectiveness cannot be confirmed post-approval.

Our goal was clear: for serious or life-threatening conditions where no alternative exists, where safety is not an issue, and where there is a strong suggestion of efficacy, we want FDA to give patients with serious medical needs *access to* products they need and desire. We believe the fast track authority can accomplish that goal. We look forward to seeing the Agency proceed with implementation of this important new authority,

Sincerely,

Jim Greenwood

Mike Bilirakis

Richard Burr